TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
170.36	50	1	50	150	7,500
570.36	10	1	10	150	1,500
Total					9,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
170.36(c)(v)	50	1	50	15	750
570.36(c)(v)	10	1	10	15	150
Total					900

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The reporting requirement is for a proposed rule that has not yet been issued as a final rule. In developing the proposed rule, FDA solicited input from representatives of the food industry on the reporting requirements, but could not fully discuss with those representatives the details of the proposed notification procedure. FDA received no comments on the agency's estimate of the hourly reporting requirements, and thus has no basis to revise that estimate at this time. During 1998, FDA received 12 notices that were submitted under the terms of the proposed rule; between January 1, 1999, and November 30, 1999, FDA received 23 notices. To date, the number of annual notices is less than FDA's estimate; however, the number of annual notices could increase when the proposed rule becomes final.

Dated: November 10, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 99–32681 Filed 12–16–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98F–1199]

Avecia, Inc.; Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a food additive petition (FAP 7B4525) proposing that the food additive regulations be amended to provide for the safe use of 2-methyl-4,5-trimethylene-4-isothiazolin-3-one as a preservative for paper coatings intended for use in contact with aqueous food.

FOR FURTHER INFORMATION CONTACT: Mark A. Hepp, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3098.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of January 6, 1999 (64 FR 884), FDA announced that a food additive petition (FAP 7B4525) had been filed by Zeneca Biocides, Foulkstone 1405, 2d, 1800 Concord Pike, P.O. Box 15457, Wilmington, DE 19850–5457. The petition proposed to amend the food additive regulations in § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) to provide for the safe use of 2-methyl-4,5-trimethylene-4-isothiazolin-3-one as a preservative for paper coatings intended for use in contact with aqueous foods. Since publication of the filing notice, Zeneca Biocide's specialty chemicals group has been spun-off as Avecia, Inc., 1405 Foulk Rd., P.O. Box 15457, Wilmington, DE 19850–5457. Avecia, Inc., has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: November 29, 1999.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 99–32682 Filed 12–16–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0969]

Guidance for Industry: Consideration of the Human Health Impact of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals (GFI #78); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance document entitled ''Guidance for Industry: Consideration of the Human Health Impact of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals'' (GFI #78). After the agency considered public comments on a draft of this guidance, announced in the **Federal Register** of November 18, 1998, it determined that revision of the draft guidance was necessary. GFI #78 announces that FDA believes that it should consider the potential human health impact of the microbial effects associated with all uses of all classes of antimicrobial new animal drugs intended for use in food-producing animals when approving such drugs. For additional information regarding the subject matter dealt with in GFI #78, see the notice of availability of the document entitled ''FDA Response to Comments on a Proposed Framework for Evaluating and Assuring the Human Food Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing